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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,011	09/30/2003	Lynn Dickey	040989/267934(9280-12A)	5538

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EXAMINER

FOX, DAVID T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/675,011	<b>Applicant(s)</b> DICKEY ET AL.	
	<b>Examiner</b> David T. Fox	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE(1) MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/30/03; 2/10/05; 3/24/05</u> | 6) <input type="checkbox"/> Other: ____.  |

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, 18-22, 25-27, and 29-30, drawn to a method of producing human growth hormone comprising transforming duckweed with a construct comprising a human growth hormone-encoding sequence operably linked to a signal sequence and an intron, wherein duckweed-preferred codons are utilized; followed by isolation of the human growth hormone from the culture medium; classified in class 435, subclass 69.4, for example.
- II. Claims 8-17, 23-24, and 28, drawn to a method of producing antibodies in duckweed comprising transforming duckweed with a construct comprising an antibody-encoding sequence operably linked to a signal sequence and an intron, wherein duckweed-preferred codons are utilized; followed by isolation of the antibodies from the culture medium; classified in class 800, subclass 288, for example.
- III. Claims 31-40, drawn to a method of producing human interferon in duckweed comprising transforming duckweed with a construct comprising an interferon-encoding sequence operably linked to a signal sequence and an intron, wherein duckweed-preferred codons are utilized; followed by isolation of the human interferon from the culture medium; classified in class 435, subclass 69.51, for example.
- IV. Claim 41, drawn to human growth hormone, classified in class 530, subclass 399, for example.

- V. Claim 42, drawn to an antibody, classified in class 530, subclass 387.1, for example.
- VI. Claim 43, drawn to alpha-interferon, classified in class 530, subclass 351, for example.
- VII. Claims 44-45, drawn to a method of enhancing the production of biologically active polypeptides via duckweed transformation with a duckweed RUBISCO leader sequence, classified in class 536, subclass 24.1, for example.

The inventions are independent or distinct, each from the other because:

Inventions I-III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In the instant case, the inventions as claimed have materially different designs, modes of operation, functions and effects; since each involves biochemically and genetically divergent sequences encoding biochemically and physiologically divergent end-products with divergent functions, namely growth hormone, antibodies or interferon. Moreover, the multicomponent-encoding sequences and light/heavy chain assembly of Group II is not required by any other group. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as isolation from native tissue, or isolation from transformed non-duckweed plants or transformed bacterial or animal cells.

Inventions II and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as isolation from native tissue, or isolation from transformed non-duckweed plants or transformed bacterial or animal cells.

Inventions III and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as isolation from native tissue, or isolation from transformed non-duckweed plants or transformed bacterial or animal cells.

Inventions VII and each of inventions I-III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs, modes of operation, functions and effects.

The invention of Group VII requires a multitude of non-hormone, non-antibody, and non-interferon-encoding sequences, such as sequences encoding biologically active polypeptides such as fungal enzymes, bacterial or fungal enzymes, blood clotting factors, microbial or insect-derived toxins, etc., each not required by Groups I-III. The inventions of Groups I-III require duckweed-preferred codons, signal sequences and methods for product isolation from culture medium, introns, and particular hormone- or antibody-encoding sequences; each not required by Group VII. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs, modes of operation, and effects.

Each invention involves physiologically and biochemically divergent proteins with different modes of action and different effects, and different amino acid sequences with no conserved regions.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, classification, and fields of search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 25, 2006

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180 1638

